

REMARKS

The undersigned, on behalf of the Applicants, would like to thank Examiner Roberts and her Supervisor, Examiner Krass, for extending the courtesy of a telephonic interview on September 19, 2008, wherein we discussed the impropriety of the pending rejections. Applicants request reconsideration of this patent application in view of the above amendments and the following remarks.

I. Status of Claims

Claims 158-164, 166-202, 205-207, 215 and 216 are pending in the application. In the Office Action mailed October 17, 2007, the Examiner declared claims 158-164, 166-202 and 205-207 as being allowed. The Examiner also indicated claims 215-216 would be allowed if they were to be written in an independent form to include all limitations of their base claims. Therefore, Applicants in their response filed February 18, 2008, rewrote claims 215 and 216 in the independent form to include all the limitations of their base claims. However, in the new Office Action dated May 28, 2008, the Examiner has rejected all the claims allegedly based on the newly cited reference.

Despite Applicants' strenuous disagreement with the alleged rejections and in the interest of expediting the prosecution, the independent claims 158, 173, 187, 215 and 216 presented herein are amended to further define the invention. Support for the new amendment can be found at paragraphs 0019-0025.

II. Summary of the Arguments

Applicants respectfully argue that: (1) the new indefiniteness rejections of claims under 35 U.S.C. § 112 is scientifically and legally flawed and further lack a clear reasoning; (2) the rejections under 35 U.S.C. § 103(a) based on the newly cited reference are improper for at least three reasons: (a) improperly combining the teachings of unrelated field of art, (b) lack of

suggestion and motivation to combine the references, and (c) the extensive hindsight picking and choosing required for the rejections; finally with respect to the obviousness rejection, (3) even if the combination of references is justified, it would not render the invention of the instant application obvious, because all limitations of the claimed invention are not described in the combined teachings of the references.

A. Rejections of claims 158-164, 166-172, 187-202, 205-207, and 215-216 under 35 U.S.C. § 112 should be withdrawn.

The Examiner rejects claims 158-164, 166-172, 187-202, 205-207, and 215-216 under 35 U.S.C. §112, second paragraph, as being indefinite for “failing to particularly point out and distinctly claim the subject matter” of the invention.

As an initial matter, Applicants note that the instant ground of rejection is not based upon any newly cited reference(s), therefore, it is not clear why such rejection has now been raised after said claims were previously rendered allowable. Nevertheless, the rejections are improper as they are void of any legal or scientific rationale.

Examiner rejected claims 158 and 187 by asserting that the limitation “wherein the patch has adhesive strength, and wherein the adhesive strength of the patch will increase upon becoming hydrated” is indefinite. The reasoning behind such rejection, if any, is not clearly stated. It appears that the Examiner is suggesting that when the claimed patch is dry, it necessarily has no adhesive strength, implying that a patch cannot be both dry and have adhesive strength. In taking such conclusory position, the Examiner does not provide any scientific or legal basis or evidence. It is simply not clear why the Examiner has taken the position that dry patches have no adhesive strengths. The claims are directed to patches that at their dry state have some adhesive strength which as demonstrated in table 2 of the present Specification can

increase substantially when hydrated. Having some adhesive strength at dry state is not the same as having no adhesive strength. For such reasons alone, this rejection should be withdrawn.

Moreover, Applicants respectfully state that Examiner's conclusion is improper, because the term dry adhesive is well understood by those of ordinary skill in the art and further has proper basis in the body of the instant Specification. The Examiner's attention is specifically drawn to pages 5-8, and 32-36, specially table 2, wherein the patch is clearly defined to possess adhesive strength in the dry state. Moreover, "dry adhesives" are abundant and well described in the art. Examples of patents directed to such products include US Patents 6,432,551 and 5,635,010. Other known commercial products such as Scotch® tapes and Band-aid® are other examples of products comprising an adhesive strength when in dry state. Contrary to the nature of the present invention, such products have adhesive strength in a "dry state," but the adhesive strength is weakened when said products come in contact with water.

In the instant Specification, Applicants designed a tooth-whitening patch which requires an adhesive that would possess a distinct property, i.e., it has some adhesive strength in a dry state and the adhesive strength becomes stronger when the patch is hydrated. The hydrophilic glassy polymer as disclosed in the Specification, pg. 17, ll. 17-21, among other ingredients, are one of the components that attribute to the strength of the dry adhesive of the presently claimed products. Accordingly, for such reasons the rejection at issue should be withdrawn.

The Examiner also rejects claims 205, 215-216, and 188 under 35 U.S.C. § 112, second paragraph, based upon the same assumption that the adhesive on the tooth-whitening patch cannot both be dry and have adhesive strength. Since the characteristics of the dry patch have been clearly defined in the Specification and those of ordinary skill in the art can understand the meaning of the term, as evidenced by the issued patents described above, such ground of

rejection should also be withdrawn, because the phrases at dispute have a clear meaning. Subsequently, Applicants respectfully request that the rejections of claims 158-164, 166-172, 187-202, 205-207, and 215-216 under 35 § U.S.C. 112, second paragraph, be withdrawn.

B. Prior Art Rejections of Claims under 35 U.S.C. § 103(a) – Obviousness

(1) Rejections of claims 158-164, 158-180, 183-195, 198-202, 205-207, and 215-216 over McAnalley et al. (US 5,409,703, hereinafter “McAnalley”) in view of Jenkins et al. (US 4,940,587, hereinafter “Jenkins”) and Chen (US 5,641,530, hereinafter “Chen”) should be withdrawn.

As an initial matter, Chen is from an entirely different field of endeavor and has nothing to do with cosmetic or pharmaceutical products, nonetheless, tooth-whitening patches. Moreover, the teachings of Chen does not add anything new to the prior cited references and are merely cumulative as to the already considered prior art. Applicants respectfully submit that the only way one of ordinary skill in the art could combine the teachings of Chen with those in McAnalley and Jenkins would be by employing improper hindsight.

McAnalley, the principal prior art cited by the Examiner in making the rejections, is a reference for wound dressings that are used as dry foams in mucosal lesions or tissue wounds. Particularly, McAnalley disclosed a hydrogel of hydrophilic-hygroscopic polymers which is used as a drug delivery device, such as wound dressing. The products of McAnalley are designed to facilitate wound healing in traumatized area to absorb excess fluid. *See* col 12, ll 20-28. McAnalley does not teach any type of products that can adhere to enamel of teeth, not to mention the instantly recited contact area width.

The only parts in McAnalley that could remotely suggest oral application of McAnalley’s products is at columns 21-22. However, a closer survey of such teachings clearly proves that the McAnalley’s dry foam is to facilitate the healing process in dental lesions, oral mucosal wounds and aphthous ulcers, all of which are wounds associated with mucosal or epithelial tissues. *See*

col 21, l. 25-col 22, l. 12. There is absolutely no teachings in McAnalley to direct those of ordinary skill in the art towards the use of McAnalley's foams on the surface of teeth. Therefore, there would have been no motivation to even use the teachings of McAnalley as the basis for denying patentability of a tooth-whitening patch having specific contact area width.

Jenkins, on the other hand, is directed to sustained release buccal pharmaceutical tablets for the use in oral or nasal cavity, both in the field of sustained release pharmaceutical administration. Further, as the Examiner has noted, Jenkins does not even disclose the incorporation of hydroxypropylmethyl cellulose into compositions comprising hydrogen peroxide, tripolyphosphate and polyvinyl pyrrolidone. OA at pg. 4. Nevertheless, the Examiner takes the position that due to "**at times**" interchangeable use of hydroxyalkyl cellulose polymers in compositions that deliver pharmaceuticals to the mucosa of the oral cavity, it would be obvious to replace one, i.e., hydroxypropylmethyl cellulose, with the other, i.e., hydroxyethyl cellulose, in designing a tooth-whitening patch.

Applicants respectfully submit that nothing can be closer to the use of improper hindsight in formulating the present rejection. By making such assertions, the Examiner has, among many, overlooked multiple essential and pivotal facts. First, none of the cited references describe oral patches or are directed to such products. Therefore, Applicants are at loss as to why those of ordinary skill in the art would be interested to combine the teachings of McAnalley and Jenkins to prepare a tooth-whitening patch.

Even if possible, the Examiner herself agrees that only "**at times**" hydroxyalkyl cellulose polymers are interchangeable. Yet, there is no reason provided to justify that the instant case is one of such occasions where the proposed interchangeability of hydroxyalkyl cellulose would

have been foreseen by those of ordinary skill in the art for preparing a tooth-whitening patch or an antimicrobial product.

Second, McAnalley and Jenkins are in fact from two entirely different field of technology. Moreover, the function and purpose of the material used in their products are different when they are used in their own fields. The Examiner relies on the ruling in *Ruff*, to justify combination of the teachings. However, McAnalley describes dressings for treatment of wounds by absorbing extra exudates generated during tissue regeneration. Jenkins on the other hand are directed to making buccal tablets with sustained release properties. There is no scientific or legal reason or motivation as to why one of ordinary skill in the art would combine the teachings of a wound dressing art with those of oral tablets to create a tooth-whitening patch. In other words, Applicants do not see the rationale that it would have been obvious to combine the teachings of McAnalley with Jenkins to design a tooth-whitening patch as disclosed in the instant application even if some material can be interchanged. The Examiner's approach is nothing but improper hindsight picking and choosing components among lists of many, particularly because Jenkins disclosed numerous possible materials having no connection with those in McAnalley.

Chen is directed to disinfection of foodstuff in the food processing industry. It is not clear to the Applicants as how this teaching is even relevant. Chen is the new reference cited by the Examiner in making the rejections which is mainly directed to disinfection of foodstuff. Although the disclosure includes the combination of hydrogen peroxide and sodium tripolyphosphate, the main teaching of the reference is that the combination of hydrogen peroxide with sodium benzoic acid or with phosphoric acid is more effective disinfectants for foodstuff than hydrogen peroxide and sodium tripolyphosphate. Therefore, Chen in fact teaches

away from the use of hydrogen peroxide in combination with sodium tripolyphosphate, even for its own intended use. *See, e.g.*, col. 2, ll. 55-62.

Moreover, the purpose of use of polyphosphate in the instant application is different from what was disclosed in Chen. In Chen, polyphosphate was disclosed as an anti-microbial agent, and its combination with hydrogen peroxide served the same purpose, as acknowledged by the Examiner (OA at p. 4), whereas in the instant application, polyphosphate was used as a “whitening aid agent” (Specification, pg. 26, ll. 7-8).

In addition, Chen, as a newly cited reference, is cumulative at most in aiding the Examiner for examining the instant application. In the Specification, Applicants have clearly described the known effects of hydrogen peroxide and polyphosphates, including sodium tripolyphosphate, in whitening teeth. *See, e.g.*, p. 26, middle paragraph. Therefore, Applicants can reasonably assume that the Examiner had considered the information in issuing the Office Action dated January 29, 2007, where the Examiner essentially allowed all the pending claims now rejected. Even if the Examiner can disagree on the cumulative nature of Chen in aiding examination of this application, the reference certainly has not risen to the level of making the combination of hydrogen peroxide with sodium tripolyphosphate an obvious reagent of choice for the tooth-whitening patch.

Therefore, the newly cited reference, the Chen patent, is from a field unrelated to both the instant application and McAnalley or Jenkins. None of the three references used in the rejections is relevant to the tooth-whitening technique and the withdrawal of the previously determined allowable claims are merely improper and contrary to USPTO’s mandate.

Finally, even if the Examiner had justifiably combined the three references in making the rejections, Jenkins and Chen would not remedy the shortcomings of McAnalley in rendering the instant invention obvious under 35 U.S.C. § 103(a).

Assuming *arguendo* that it was proper for the Examiner to combine McAnalley with Jenkins and Chen, it is still improper to make a blanket rejection of the claims listed, because the Examiner would have ignored the other limitations in the claims that are not taught by the three references.

Claims 158 and 187 define the tooth whitening patch wherein it has a specific contact area width “in a dry state. . . wherein the patch has adhesive strength, and wherein the adhesive strength of the patch will increase upon becoming hydrated by applying the patch to a user's teeth.” Likewise, claim 173 contains the limitation “wherein the patch is in a dry state such that about 10% or less of the materials will adhere to a dry surface upon contact with the surface, and is adapted to strongly adhere to a user's teeth upon becoming hydrated when applied to such a user's teeth.”

Claims 215 and 216 define the tooth whitening patch comprising two layers, “wherein one of the layers is an active ingredient-containing adhesive layer for application to teeth . . . wherein the adhesive layer is in a dry state and has adhesive strength,” and “wherein the adhesive strength of the adhesive layer will increase upon becoming hydrated by applying the adhesive layer to a user's teeth.” None of the cited references disclosed the above limitations.

It is respectfully submitted that a proper 35 U.S.C. § 103(a) rejection requires that the prior art cited render all the limitations of the claims obvious to a person of ordinary skill in the art. Here, all the references combined would not render the above mentioned limitations obvious, even if the hindsight picking and choosing were proper in arriving at the combination of

the ingredients. In fact, the tooth-whitening patch in a dry state in the instant application is not obvious because it was designed to overcome the shortcomings that have long existed in other competing products on the market. *See Background of Invention.*

Therefore, the rejections of claims 158, 173, 187, 215, 216, and all the other claims dependent thereon under 35 U.S.C. § 103(a) should be withdrawn.

(2) Rejections of claims 166, 181, 182, 196, and 197 as being unpatentable over McAnalley in view of Jenkins and Chen as applied to claims 158-164, 168-180, 183-195, 198-202, 205-207, 215 and 216 in further view of Frate et al. (US 2001/0049417, hereinafter "Frate") should be withdrawn.

First, Applicants respectfully submit that the rejections of dependent claims 166, 181, 182, 196, and 197 should be withdrawn because combination of McAnalley with Jenkins and Chen did not meet the threshold requirement of 35 U.S.C. § 103(a) for all the limitations defined in claims 158, 173, 187, as described above.

In these rejections, the Examiner again tried to equate the invention of the present application with the sum of the four references cited. In doing so, the Examiner relied on the rejections of claims 158, 173, and 187 by combining McAnalley, Jenkins, and Chen. As discussed above, the three references are all cited from different fields than that of the present application and there is lack of motivation and suggestion to combine the three references. In fact, as discussed above, even combination of the three references were proper under 35 U.S.C. § 103(a), the combination would not reach the invention disclosed in the instant application; therefore, rejections of independent claims 158, 173, and 187 are improper under 35 U.S.C. § 103(a).

Second, even though Frate disclosed the plasticizer element of the claims 166, 181, 182, 196, and 197, as the Examiner asserted, combination of the four references are still short of reaching the rejected claims, because at least none of the four references disclosed the limitation

of a tooth whitening patch “in a dry state,” “wherein the patch has adhesive strength, and wherein the adhesive strength of the patch will increase upon becoming hydrated by applying the patch to a user’s teeth,” or the contact area width.

Moreover, although the Examiner could expediently pinpoint “humectants such as glycerin, propylene glycol and sorbitol” as the additives of the hydrogel in the disclosure of Frate, the Examiner could not have done so absent hindsight relying on the present application. In fact, Frate disclosed a virtually unlimited number of possible additives for a hydrogel, yet without specifically teaching why the humectants the Examiner cited should be chosen. The Examiner in making the rejections, relies on Frate’s disclosure that essentially teaches that everything could be an additive for the hydrogel, that is, indeed, “a general teaching” as the Examiner stated (OA, p. 5, bottom); therefore, the Examiner made this ground of rejection based on a hindsight picking and choosing, which would otherwise be impossible. It is certainly not as simple as the Examiner concluded: “The reference differs from the instant claims insofar as it does not disclose the plasticizers are incorporated into compositions comprising hydrogen peroxide and polyvinyl pyrrolidone.”

Although Applicants acknowledge that hindsight picking and choosing are allowed to some degree in making the section 103(a) rejections, as instructed by the MPEP 737.03, here the claimed invention is directed to a specific composition, instead of a genus, in a field different from all the cited references.

“To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” MPEP 706(j)

(citing *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)). Applicants respectfully submit that, similar to the rejections of all the claims discussed in the previous section, the rejections of claims 166, 181, 182, 196, and 197 under 103(a) over McAnalley, Jenkins, Chen, and Frate are lack of convincing line of reasoning as to why a person of ordinary skill in the tooth-whitening art would have found the invention obvious without aid of extensive hindsight picking and choosing. Therefore, Applicants respectfully request that the rejections of claims 166, 181, 182, 196, and 197 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

Claims 158-164, 166-202, 205-207, and 215-216 are pending. Pursuant to the arguments presented above, Applicants respectfully request that all the rejections in the Office Action dated May 28, 2008, be withdrawn and all the pending claims be allowed.

Applicants request that any questions concerning this matter be directed to the undersigned at 609-844-3030. If a telephone conference would be of assistance in advancing the prosecution of the present application, Applicants' undersigned attorney invites the Examiner to telephone at the number provided.

Applicant also authorizes the charge of any deficiency and/or the credit of any overpayment to Deposit Account No. 50-1943.

Please date stamp and return the enclosed postcard evidencing receipt of this document.

Respectfully submitted,

/Shahnam Sharareh/

Shahnam Sharareh, PharmD, Esq.
Registration No. 59,040
Attorney for the applicants
Fox Rothschild LLP
Princeton Pike Corporate Center
997 Lenox Drive, Building 3
Lawrenceville, NJ 08648-2311
Telephone: (609) 844-3030
Facsimile: (609) 896-1469